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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,285	02/01/2002	Greg Fahy	074066-0115	3778

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FOLEY & LARDNER

P.O. BOX 80278

SAN DIEGO, CA 92138-0278

EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,285	FAHY ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,36-57 and 59-68 is/are pending in the application.
- 4a) Of the above claim(s) 52-57 and 59-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,36-51,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/12/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6, 36-57, 59-68 are pending. Claims 1-6, 36-51, 67 and 68 are considered on the merits. Claims 52-57, 59-66 are withdrawn from consideration as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 36-51, 67 and 68 are provisionally rejected under the judicially created doctrine of double patenting over claims 6, 18, 21 of copending Application No. 09/916396. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending

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application and the instant application are claiming common subject matter, as follows: a solution comprising lactose and polyglycerol.

Claim Rejections – 35 USC § 112

INDEFINITE

Claim 51 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 51, the recitation refers to “impermeant species”. The term “impermeant” with regard to compounds does not have a specific meaning in the art. Please note that the same compound, glucose, is said to be an impermeant chemical in US 6,194,137 (col. 6, l. 41) while in US 5,800,978 (col. 15, l. 34) it is said to be a “permeable compound”. Thus, the term, impermeant, is not indicative of any metes and bounds because the same compound can be said to be both a permeant and an impermeant.

Response to Arguments

Applicant argues that the term “impermeant” is classified based on their behavior in a particular context. Applicant further states that if the permeation is “very slow” compared to the amount of a compound present, the compound is considered to be impermeant in practice. This explanation does not, however, further limit in what context the solution will be employed and what the term “very slow” which is a term of comparison, means in absolute values. Further, Applicants have not explained how one of ordinary skill in the art can define glucose as both a permeable and an impermeable compound in reference to permeation through a cell membrane. In ‘978, col. 8, ls. 52–60, glucose is clearly defined as a permeant, that is, a cell membrane permeating compound. In ‘137, glucose is clearly cited as being a cell membrane impermeant compound. These terms appear to be used in the same context by those of ordinary skill in the art. The argument is not well taken and the rejection remains.

Claim Rejections – 35 USC § 103

Claims 1–6, 36, 50, 51, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,19,137 [B] in view of US 6,616,858 [A] or Klebe *et al.* [U].

The claims are directed to a solution comprising lactose and polyglycerol for use as a preservation solution for cells, organs, tissues under hypothermic conditions. Dependent claims are directed to the osmolality of the impermeant species and the inclusion of glutathione in the solution.

The references are relied upon as explained below.

US 6,616,858 discloses that solutions comprising polyglycerol protect tissues and organs under hypothermic conditions.

Klebe *et al.* disclose that decaglycerol is a cryoprotective agent (Table 1).

US 6,194,137 discloses that lactose has cryoprotectant properties (col. 6, l. 41). Further, that any combination of cryoprotectants may be contained in a cryoprotectant solution (col. 6, l. 23). The disclosure is not limited to the use of any amount of lactose or other cryoprotectant. Glutathione is a component of several common preservative solutions as shown in Tables 2 and 3.

The addition of a polyglycerol to the solution of US 6,194,137 would have been obvious when the disclosures of either Klebe *et al.* or US 6,616,858 were taken because Klebe *et al.* and US 6,616,858 both teach that polyglycerol is a cryoprotectant and US 6,194,137 states that any cryoprotectants may be components of the cryoprotective solution.

One of ordinary skill in the art would have been motivated at the time of invention to make this combination of compounds in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably

distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

The formulation of the obviousness rejection has been clarified above. Applicants are thanked for the attention paid to the ground of rejection.

Applicants argue that an unexpected result has been shown when polyglycerol and lactose are combined in concentrations effective to preserve tissues.

Applicants argue that the prior art only offers "laundry lists" of cryopreservatives. While it may be true that the prior art has only a listing of suitable cryoprotective compounds, the rejected claims are not commensurate in scope with applicants' allegations of unexpected results. The unexpected results obtained with the solution is due to the concentrations of the two components, polyglycerol and lactose, which is not in any pending claim.

Allowable Subject Matter

The inclusion of claims 5 and 6 into claim 1 may result in an allowable claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651